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| 10/500,868 | 07/21/2004 | Jean-Pierre Devidal | 021305-00201 | 8688 |

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| EXAMINER |
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ALSTRUM ACEVEDO, JAMES HENRY

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| ART UNIT | PAPER NUMBER |
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1616

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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|---|---------------------------------------|
| Office Action Summary | Application No. 10/500,868 | Applicant(s) DEVIDAL ET AL. |
| | Examiner James H. Alstrum-Acevedo | Art Unit 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-4, 7-8, and 10-16 are pending. Claims 10-16 have been withdrawn from consideration as being drawn to a non-elected invention.¹ **Claims 1-4 and 7-8 are under consideration in the current office action.** Applicants previously cancelled claims 6 and 9. Applicants have newly cancelled claim 5. Applicants have amended claims 1, 4, and 7. Receipt and consideration of Applicants' amended claims and remarks/arguments, submitted on July 24, 2006 is acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2007 has been entered.

Moot Rejections/objections

All rejections and/or objections of claim 5 cited in the previous office action mailed on October 16, 2006 **are moot**, because said claim has been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

¹ Election was made without traverse in the reply filed on January 20, 2006.

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** per Applicants' amendments correcting the indefinite language and lack of antecedent basis cited on page 2 of the office action mailed on October 16, 2006.

Response to Arguments

Applicant's arguments, see page 6, filed January 16, 2006, with respect to the rejection of claims 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been fully considered and are persuasive. The rejection of claims 4 under 35 U.S.C. 112, second paragraph has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims

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2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-4 and 7 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963) **is withdrawn** per Applicants' amendments requiring that the sprayed liquid is sucked from the skin by means of a conduit in communication with a vacuum pump.

Response to Arguments

Applicant's arguments, see page 6, filed January 16, 2006, with respect to the rejection of claims 1-4 and 7 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963) have been fully considered and are persuasive. The rejection of

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claims 1-4 and 7 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963) has been withdrawn.

The rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963) and further in view of Laughlin (U.S. 2002/0000237) and/or Yu et al. (5,962,526) **is withdrawn** per Applicants' amendments requiring that the sprayed liquid is sucked from the skin by means of a conduit in communication with a vacuum pump.

Response to Arguments

Applicant's arguments, see page 6, filed January 16, 2006, with respect to the rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963) and further in view of Laughlin (U.S. 2002/0000237) and/or Yu et al. (5,962,526) have been fully considered and are persuasive. The rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963) and further in view of Laughlin (U.S. 2002/0000237) and/or Yu et al. (5,962,526) has been withdrawn.

Claims 1-4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061), Laughlin (U.S. 2002/0000237), Weber et al. (US 2002/0058952) and/or Yu et al. (5,962,526).

Applicant Claims

Applicants claim a method for the treatment of an area of human skin comprising the steps of (i) abrading a portion of the stratum corneum (i.e. the outermost layer of skin) followed by (ii) spraying a pressurized liquid onto the area to be treated by means of a spray nozzle and sucking the sprayed liquid from the skin by means of a conduit in communication with a vacuum pump, wherein the liquid comprises water or saline (claim 2) or at least one additive (claim 3), wherein the spraying step comprises spraying a liquid at a maximum pressure such that there is no risk of breaking the skin at a pressure of between 10 and 25 bar (claim 4), wherein the suction step is performed by reducing pressure of a volume surrounding the treated area of skin (claim 7), and/or further comprising the steps of (iii) filtering the liquid removed from the sucking step and (iv) recycling it.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Bode and Rhoades were set forth on pages 4-5 (Bode) and 9-10 (Rhoades) of the office action mailed on January 10, 2006 and are incorporated herein by reference in their entirety. The teachings of Laughlin and Yu were set forth on pages 8-10 of the

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office action mailed on October 16, 2006. The teachings of Weber were alluded to on page 10 of the office action mailed on October 16, 2006, but are explicitly set forth herein below.

Weber teaches tissue resurfacing using biocompatible materials using a device comprising a vacuum line near the delivery tip which may be used to remove excess materials or reaction-products that bind up on the surface of the skin (title, abstract). The vacuum line is comprised of an opening near the tip connected to a vacuum pump via a cable ([0034]-[0035]). A vacuum pump connected via a cable reads on “a conduit in communication with a vacuum pump.”

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Bode, Rhoades, Hirota, Laughlin, and Yu lack the teaching of a method utilizing a sprayer or other device that comprises a conduit in communication with a vacuum pump to suck up sprayed liquid from the skin. This deficiency is cured by the teachings of Weber.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art to combine the teachings of Weber with the combined teachings of Bode, Rhoades, Laughlin, and Yu (“BRLY combination”), because all the inventors teach methods, devices, and/or compositions used in treating the skin. The BRLY combination effectively teaches the desirability of recovering or filtering residual composition used in a method of treating the skin. It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant

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invention to utilize a system or device that contained a vacuum pump to remove debris liquid resulting from the methods of the BRLY combination. It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention that a vacuum source, such as taught by Weber, could “suck up” liquid, if applied to said liquid. Because it has been demonstrated above that the inclusion of a vacuum source in a device used to treat the skin is desirable and both common sense and common knowledge in the art would recognize that the application of vacuum to an area having a liquid would result in said liquid being “sucked up”, an ordinary skilled artisan would have had a reasonable expectation of success upon combination of Weber’s teaching with the teachings of the BRLY combination. Regarding the limitation that the liquid be sprayed at a pressure between 10-25 bar, Bode teaches the use of a liquid pressure of 8 bar. It would have been *prima facie* obvious to optimize the liquid pressure to maximize sub-cutaneous drug delivery, because liquid pressure is a result effective parameter in the subcutaneous delivery of actives by application of a jet of liquid (i.e. pressurized liquid). Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments filed January 16, 2007 have been fully considered but they are not persuasive. Applicants' arguments as they may apply to the instant rejection are addressed herein below. Applicants' addressed the previous rejection of record based upon the combination of Bode with various secondary references by attacking each reference individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by

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attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants' combined arguments against the individual references were that the prior art allegedly does not teach: (1) abrading the stratum corneum; (2) "sucking the sprayed liquid;" (3) Weber discloses that the propelled materials should be maintained in solid form for maximal capability, which is in contrast to Applicants' claimed methods requiring the spraying of a pressurized liquid; and (4) the action of the spraying the pressurized liquid creates a vacuum on the surface of the skin that can create a depression of the surface of the skin causing hyperemia.

The Examiner respectfully disagrees with Applicants' traversal arguments. The Examiner submits that microdermabrasion (Rhoades) reads on abrading the stratum corneum, because it removes the top layer of skin. It is known in the art that the stratum corneum is the outermost layer of skin comprised of dead skin cells. Abrasion means the wearing away or removal of. Thus, abrading the stratum corneum means the wearing away or removal of the stratum corneum, which is taught by the prior art. Weber teaches the sucking of sprayed liquid, as set forth above in the instant office action, and thus (2) is unpersuasive. Argument (3) is unpersuasive, because Applicants' have ignored the teachings of the combined art, which teaches the spraying of a liquid, and the rejected claims do not preclude active or therapeutic agents from being present in solid form nor do they require that these be dissolved in the sprayed liquid.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sprayed liquid

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creates a vacuum on the surface of the skin that can create a depression of the surface of the skin causing hyperemia) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Notwithstanding this, even if this were included in the rejected claims it would not be persuasive, because the combined prior art references teach the same step of spraying a pressurized liquid and thus would inherently also create a localized area of vacuum on the skin resulting in hyperemia, as this is a consequence of spraying a pressurized liquid (see Applicants' arguments bridging pages 6-7).

Claims 1-4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karasiuk (US 2003/0097139), Bode et al. (DE 19606433; based on the English abstract and translation), Weber et al. (US 2002/0058952) and/or Yu et al. (5,962,526).

Applicant Claims

Applicants' claims have been described above in the instant office action.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Bode were set forth on pages 4-5 (Bode) of the office action mailed on January 10, 2006 and are incorporated herein by reference in their entirety. The teachings of Yu were set forth on page 9 of the office action mailed on October 16, 2006. The teachings of Weber were alluded to on page 10 of the office action mailed on October 16, 2006, and were explicitly set forth above in the instant office action.

Karasiuk teaches a microdermabrasion system and method of use for exfoliating skin cells from the external surface of skin (i.e. abrading the stratum corneum), wherein the device is adapted to flow one or more liquids through a chamber provided in the device, wherein upon application of vacuum, fluids are drawn up through the chamber and applied to the skin and a portion of the skin is drawn into the chamber and brought into contact with an abrasive member (title; abstract; claims 20-24). The fluids are contained with a reservoir and are delivered via the tip of the device [0017]. The device also includes a collection reservoir connected to a vacuum source, optionally with a **filter inline between the collection reservoir and the vacuum source** [0018]. Vacuum surrounding the perimeter of the abrasive member can be used to collect microabraded skin particles downstream from the abrasive member and from all locations surrounding the abrasive member (this would obviously also collect sprayed liquid) [0022]. The device contains an opening that is in communication with a vacuum source via a vacuum line [0046]. Abrasive particles used in Karasiuk's method may be used together with **lotions, vitamins, and/or other skin treatment fluids** to be applied to the skin or with other fluid carriers [0050]-[0051]. Advantageously, since the flow of fluids surrounds the area of skin being microabraded, the skin is both pretreated and post-treated with the vitamins, lotions, etc. contained in the reservoir 70. Pretreatment can soften the area of skin treatment to be microabraded, thereby rendering exfoliation more complete and easier to accomplished with less trauma to the skin tissues left behind, while post-treatment helps to reduce streaking and redness of the skin tissues left behind [0055].

Ascertainment of the Difference Between Scope the Prior Art and the Claims***(MPEP §2141.012)***

Karasiuk lacks the teaching of a nozzle and specific pressure of a sprayed liquid. This deficiency is cured by the teachings of Bode. Karasiuk lacks the express teaching of a fluid (i.e. liquid) being water or aqueous saline. This deficiency is cured by the teachings of Yu. Karasiuk lacks the express teaching of a vacuum pump. This deficiency is cured by the teachings of Weber.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art to combine the teachings of Karasiuk, Bode, Weber, and Yu, because all references are within the same field of skin treatment methods and compositions, utilizing compositions comprising pharmaceuticals and/or cosmetics (Bode and Yu) and devices for the treatment of skin (Karasiuk, Bode, and Weber). An ordinary skilled artisan would have been motivated to modify Karasiuk's device to spray liquid to affect (i.e. adjust the flow of fluids) to improve the pre- and post-treatment of skin with vitamins, lotions, and other skin treatment fluids taught by Karasiuk, because Bode's teachings enable one to deliver active agents, such as in the form of a liquid or cream, subcutaneously without the use of needles. Yu sets forth that the art recognizes that suitable skin treatment formulations include aqueous formulations having dissolved therein additives, such as penetration enhancers, in addition to actives. An ordinary skilled artisan would have been motivated to utilize formulations, such as those taught by Yu, because this are suitable for the treatment of skin and Karasiuk teaches fluids comprising vitamins, lotions, and other skin

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treatments. It would have been obvious to an ordinary skilled artisan to use a vacuum pump as a source of vacuum, because common sense and common knowledge in the art indicates that vacuum pumps are a source of vacuum (Weber). An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art references, because the art recognizes (1) the use of pressurized fluids to deliver pharmaceutical or cosmetic agents; (2) microdermabrasion exfoliates skin (i.e. abrades the stratum corneum); (3) aqueous solutions are suitable for skin treatment; and (4) vacuum pumps are well-known sources of vacuum. Regarding the limitation that the liquid be sprayed at a pressure between 10-25 bar, Bode teaches the use of a liquid pressure of 8 bar. It would have been *prima facie* obvious to optimize the liquid pressure to maximize sub-cutaneous drug delivery, because liquid pressure is a result effective parameter in the subcutaneous delivery of actives by application of a jet of liquid (i.e. pressurized liquid). Therefore the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are considered relevant because these teach devices and/or methods of (micro)-dermabrasion (i.e. abrasion of the stratum corneum), and in many instances the devices utilize vacuum to suck up liquid and/or debris: U.S. Patent No. 6,695,853 (Karasiuk); U.S. Patent No. 6,264,666 (Coleman et al.); U.S. Patent No. 6,500,183 (Waldron); US 2001/0049511 (Coleman et al.), and US 2003/0060834 (Muldner).

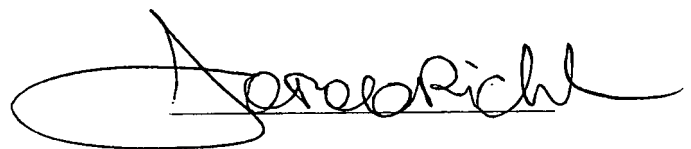
Claims 1-4 and 7-8 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Patent Examiner
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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning.

Johann Richter, Ph. D., Esq.
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